

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

**IN RE NEW ENGLAND COMPOUNDING
PHARMACY, INC. PRODUCTS
LIABILITY LITIGATION**

MDL No. 2419
Dkt. No. 1:13-md-2419 (RWZ)

THIS DOCUMENT RELATES TO:

All Cases Against the Specialty Surgery Center Defendants

**MEMORANDUM OF LAW SUPPORTING MOTION FOR JUDGMENT ON THE
PLEADINGS REGARDING COMPARATIVE FAULT DEFENSES
ATTRIBUTING FAULT TO GOVERNMENTAL ENTITIES**

The Plaintiffs' Steering Committee respectfully submits this memorandum in support of its contemporaneously filed Motion for Judgment on the Pleadings Regarding Comparative Fault Defenses Attributing Fault to Governmental Entities.

INTRODUCTION AND SUMMARY

Contrary to well-settled principles of Tennessee law, the SSC Defendants¹ and Calisher & Associates (“Calishers”) (collectively, the “Defendants”) assert the affirmative defense of comparative fault against the following governmental entities: the Food and Drug Administration (the “FDA”), the Massachusetts Board of Registration in Pharmacy (the “MBoP”), the Tennessee Board of Pharmacy (the “TBoP”), and the Tennessee Department of Health (the “TDoH”) (collectively referred to hereinafter as the “Non-Party Governmental Entities”). Through those affirmative defenses, the Defendants intend to ask juries to allocate fault on verdict forms to non-party governmental regulators. This Court should dismiss these affirmative defenses because they

¹ The “SSC Defendants” include Specialty Surgery Center, PLLC, Dr. Kenneth Lister, and Kenneth Lister, MD, PC.

are contrary to Tennessee law. Under Tennessee law, fault cannot be attributed to government agencies because none of those agencies owed an individual legal duty to any particular Plaintiff.

Under Tennessee's public duty doctrine, the only legal duty owed by the government was owed to the general public at large, not to any particular individual. In other words, as far as Tennessee tort law is concerned, a duty owed to everyone is a duty owed to no one particular person. Accordingly, because legal duty is an essential element of fault, fault cannot be allocated to governmental entities at trial.

**MATERIAL FACTS ASSERTED IN PLEADINGS THAT FORM THE BASIS OF
COMPARATIVE FAULT DEFENSES**

In their Answers to Plaintiffs' Master Complaint, the SSC Defendants and Calishers assert the affirmative defense of comparative fault against the FDA, the MBoP, the TBoP, and the TDoH, among others.² Those allegations largely relate to the Defendants' claims that those Non-Party Governmental Entities should have acted sooner and shut down NECC before the catastrophe that gave rise to this MDL.

Specifically, the SSC Defendants allege the following with regard to the FDA:

36. ...[The FDA] owed a duty to the Plaintiffs as well as their health care providers to ensure that MPA manufactured, sold, and distributed by NECC was sterile and safe for its intended use pursuant to the Federal Food, Drug, and Cosmetic Act, codified at 21 U.S.C. § 301, et seq.

² See Dkt. No. 1456, Answer of Specialty Surgery Center, Crossville, PLLC, Kenneth R. Lister, MD, and Kenneth Lister, MD, PC ("SSC Defendants' Answer"), at pp. 66-112; Dkt. No. 2926, Answer to Complaint with Jury Demand by Calisher & Associates, Inc. ("Calishers' Answer") at p. 31 (Eleventh Affirmative Defense) (incorporating SSC Defendants' comparative fault allegations by reference). The SSC Defendants also filed an Answer to certain Plaintiffs' Short Form Complaint (Dkt. No. 1460), which incorporated the SSC Defendants' Answer by reference. For ease of reference, the PSC will cite to allegations in the SSC Defendants' Answer (Dkt. No. 1456) and treat those as made both by the SSC Defendants and Calishers. The PAC also notes that SSC Defendants and Calishers also assert comparative fault against a number of private entities (including each other), but that those comparative fault against private entities are not the subject of this Motion.

...

38. The Defendants assert comparative fault against the FDA for proximately causing the alleged injuries and damages by negligently or recklessly failing to take action against NECC even though the FDA had authority to do so...³

The Defendants allege similar allegations against the MBoP and the TBoP:

56. [The MBoP] owed a duty to the Plaintiffs as well as their health care providers to ensure that NECC compounded medication free from contamination and operated in compliance with applicable Massachusetts pharmaceutical laws pursuant to Mass. Gen. Laws ch. 112, § 32.

....

57. The Mass. BoP breached this duty, proximately causing all injuries and damages alleged

...

66. The Mass. BoP proximately caused the alleged injuries and damages by negligently or recklessly failing to discipline or take action against NECC after becoming aware of NECC's failure to comply with applicable state and federal laws and manufacturing guidelines...

....

72. [The TBoP] had the legal authority to inspect NECC, which was doing business in Tennessee as a licensee of the Tenn. BoP.

...

74. If it is established that the Tenn. BoP breached its duty by failing to timely investigate and bring charges against NECC for the violations outlined herein, failing to inquire of the Mass. BoP regarding actions against NECC, or failing to inspect NECC's facility, the Defendants assert fault against the Tenn. BoP.⁴

³ Dkt. No. 1456, SSC Defendants Answer, at ¶¶ 36 and 38. ¶¶ 36-55 allege comparative fault against the FDA.

⁴ Dkt. No. 1460, SSC Defendants Answer, at ¶¶ 56, 66, 72, and 74. The comparative fault allegations against the MBoP and TBoP are set forth at ¶¶ 56-75.

The SSC Defendants also allege comparative fault against the Tennessee Department of Health based on the following allegations:

80. The Defendants promptly complied with all instructions from the Tenn. DoH and CDC regarding contacting patients, including an initial directive from the Tenn. DoH not to mention meningitis.

81. The Defendants relied upon and promptly complied with all directives and guidance received from the Tenn. DoH related to this fungal meningitis outbreak.

82. If it is established that the Tenn. DoH did not recommend appropriate notification of patients, the Defendants are constrained to assert comparative fault against the Tenn. DoH.⁵

Based on the allegations in their respective Answers, it is clear that the Defendants seek to ascribe fault to the Non-Party Governmental Entities on a theory that those entities should have done a better job of regulating NECC prior to the catastrophe of 2012, and their failure to properly regulate NECC is, in part, the cause of Plaintiffs' injuries.

RULE 12(c) STANDARD

Under Rule 12(c), "[a]fter the pleadings are closed...a party may move for judgment on the pleadings." A Rule 12(c) motion for judgment on the pleadings "is treated much like a Rule 12(b)(6) motion to dismiss."⁶ Legal conclusions are ignored and, "under Rule 12(c), courts need not credit conclusory statements or merely subjective characterizations."⁷

Because a Rule 12(c) "motion calls for an assessment of the merits of the case at an embryonic stage, the court must view the facts contained in the pleadings in the light most favorable to the non-movant and draw all reasonable inferences therefrom" in the non-movant's

⁵ Dkt. No. 1460, SSC Defendants' Answer, ¶¶ 80-82.

⁶ *Perez-Acevedo v. Rivero-Cubano*, 520 F.3d 26, 29 (1st Cir. 2008).

⁷ *Class v. Commonwealth of Puerto Rico*, 309 F. Supp. 2d 235, 236 (D.P.R. 2004); *see Soto-Torres v. Fraticelli*, 654 F.3d 153, 158-159 (1st Cir. 2011).

favor.⁸ Accordingly, "[t]here is no resolution of contested facts in connection with a Rule 12(c) motion: a court may enter judgment on the pleadings only if the properly considered facts conclusively establish the movant's point."⁹ A Rule 12(c) motion nonetheless differs from a Rule 12(b)(6) motion because it "implicates the pleadings as a whole."¹⁰ Filed after the close of the pleadings, a Rule 12(c) motion is "based solely on the factual allegations in the complaint and answer."¹¹

Whereas here, Plaintiff is the moving party, this court is obligated to view the facts in favor of Defendants as the non-moving party¹² In deciding a motion for judgment on the pleadings filed by a plaintiff, the court therefore "consider[s] only allegations of fact [that] are admitted or not controverted in the pleadings."¹³

Subject to certain narrow exceptions and absent a conversion of the Rule 12(c) motion to a summary judgment motion under the procedure set forth in Rule 12(d), this Court's review is confined to the Amended Complaint, the Answer and any attached exhibits.¹⁴ Here, the PSC maintains that judgment on the pleadings is appropriate because as alleged in their Answer, the comparative fault defenses seeking to attribute fault to the Non-Party Governmental Entities fails

⁸ *R.G. Financial Corp. v. Vergara-Nunez*, 446 F.3d 178, 182 (1st Cir. 2006).

⁹ *Id.*; accord 5C Charles Allan Wright et al., Federal Practice and Procedure § 1368 (3rd ed. 2004) ("motion for judgment on the pleadings under Rule 12(c) may be granted only if all material issues can be resolved on the pleadings by the district court").

¹⁰ *Aponte-Torres v. Univ. of Puerto Rico*, 445 F.3d 50, 55 (1st Cir. 2006).

¹¹ *NEPSK, Inc. v. Town of Houlton*, 283 F.3d 1, 8 (1st Cir. 2002).

¹² See generally *R.G. Financial Corp.*, 446 F.3d at 182.

¹³ *Swepti, LP v. Mora Cnty., N.M.*, 81 F. Supp. 3d 1075, at *1 (D.N.M. 2015) (internal quotation omitted); see also 5C Charles Allan Wright et al., Federal Practice and Procedure § 1367 (3rd ed. 2004) ("motion for a judgment on the pleadings only has utility when all material allegations of fact are admitted or not controverted in the pleadings").

¹⁴ Fed.R.Civ.P. 12(d); see Fed.R.Civ.P. 10(c) ("a written instrument that is an exhibit to a pleading is part of the pleading for all purposes").

as a matter of law, and the Court need look no further than the facts as alleged in the Defendants' respective Answers to reach this conclusion.

ARGUMENT

Judgment on the pleadings should be granted to the Plaintiffs dismissing the Defendants' Comparative Fault Defenses against the Non-Party Governmental Agencies because, under the public duty doctrine, fault cannot be attributed to these entities because the Defendants cannot establish the requirement element of individual duty.

Under Tennessee law, establishing a legal duty is an essential element of establishing fault.¹⁵ Fault cannot be established when no individual duty exists.¹⁶ "The existence or nonexistence of a duty owed to the plaintiff by the defendant is entirely a question of law for the court."¹⁷

The existence of a duty is a condition precedent to attributing fault in Tennessee. For an entity to be attributed the legal fault for any injury, a legal duty to prevent or not cause that harm must exist. A duty of care is "the legal obligation owed by defendant to plaintiff to conform to a reasonable person standard of care for the protection against unreasonable risks of harm."¹⁸ "The common law has long recognized that an individual has a duty to exercise reasonable care in his or her activities in order to prevent unreasonable risks of harm from arising."¹⁹ "While individuals have an obligation to refrain from acting in a way that creates an unreasonable risk of

¹⁵ *Eaton v. McLain*, 891 S.W.2d 587 (Tenn. 1994).

¹⁶ *Id.*

¹⁷ *Hurd v. Flores*, 221 S.W.3d 14, 18 (Tenn. Ct. App. 2006).

¹⁸ *Downs ex rel. Downs v. Bush*, 263 S.W.3d 812, 819 (Tenn. 2008).

¹⁹ *Id.*

harm to others, the law generally does not impose on individuals an affirmative duty to aid or protect others.”²⁰

Courts in Tennessee regularly dismiss claims attempting to ascribe fault to parties where no legal duty exists.²¹ As the Tennessee Supreme Court makes abundantly clear, “only after a duty is established does comparative fault come into play.”²² In the present case, fault cannot be attributed to government agencies because those agencies did not owe an individual duty to any particular Plaintiff asserting claims against the Defendants.

“As in any other negligence action, a [party] must establish the existence of a duty or standard of care in an action for negligence of a government employee.”²³ When a party asserts the fault of a public employee or entity, Tennessee courts follow a legal doctrine known as the public duty doctrine.²⁴ Under that legal principle, duties owed by public employees and agencies are owed to the general public, not to specific individuals.²⁵ Under the public duty doctrine, a

²⁰ *Id.*

²¹ See e.g., *Eaton* at 597 (dismissing claims after trial because “plaintiff has failed to present legally sufficient evidence as to the duty element on her claims...”); *Brient v. Petro PSC, L.P.*, 134 F.3d 370 (6th Cir. 1998) (dismissing claims where “as a matter of law [plaintiff] cannot establish the duty element of negligence.”); *Puckett v. Roberson*, 183 S.W.3d 643 (Tenn. Ct. App. 2005) (dismissing claims where no legal duty was shown because “[a]s a general rule, persons do not have a duty to control the conduct of other persons to prevent them from causing physical harm to others.”) *Norfleet v. Pulte Homes Tenn. Ltd. P’ship*, 2011 WL 5446068, at *6 (Tenn. Ct. App. Nov. 9, 2011) (“Therefore, as a matter of law, [plaintiff] failed to establish an essential element of her claim, that of a duty owed to her by Defendant as it pertained to the step from the foyer to the sunken living room.”).

²² *Coln v. City of Savannah*, 966 S.W.2d 34, 42 (Tenn. 1998); see also *Blair v. Campbell*, 924 S.W.2d 75 (Tenn. 1996) (“Adoption of principles of comparative fault do not alter analysis applicable to common-law concept of duty.”).

²³ *Wells v. Hamblen County*, 2005 WL 2007197, at *3 (Tenn. Ct. App. Aug. 22, 2005), citing *Ezell v. Cockrell*, 902 S.W.2d 394 at 397, 400 (Tenn. 1995).

²⁴ *Ezell*, 902 S.W.2d at 397-401.

²⁵ *Id.* at 397.

duty owed to everyone is a duty owed to no one as far as tort liability is concerned.²⁶ The Tennessee Court of Appeals explains the public duty doctrine as follows:

The public duty doctrine is a creature of common law, and its purpose is to shield a public employee from “suits for injuries that are caused by the public employee’s breach of a duty owed to the public at large.” *Ezell*, 902 S.W.2d at 397. It is sometimes explained by stating that a duty owed to everyone is a duty owed to no one. *See Brown*, 126 S.W.3d at 43.

As in any other negligence action, a plaintiff must establish the existence of a duty or standard of care in an action for negligence of a government employee. *Ezell*, 902 S.W.2d at 397, 400. In Tennessee, it has long been held that a plaintiff must show the existence of a duty particular to him or her, as distinct from a duty owed to the public in general.²⁷

Therefore, Tennessee law clearly provides that fault cannot be attributed to the Non-Party Governmental Entities because any duties owed by those agencies are owed to the general public, not to any particular plaintiff.

In *Hurd v. Flores*, for example, a motorist claimed that a police officer negligently caused the motorist’s accident by not stopping the driver from entering an interstate crossover within sight of the officer.²⁸ The Court of Appeals dismissed the matter under the public duty doctrine, stating that, although the officer had a duty to preserve the peace and arrest lawbreakers, that duty “is one which the officer owes to the public generally, and not to particular individuals, and [] the breach of such duty accordingly creates no liability on the part of the officer to an individual who was damaged by the lawbreaker’s conduct.”²⁹ Accordingly, with respect to the officer’s general public duty, the public officer’s conduct was “amenable only to the public, and punishable only by indictment for breach of his duty as conservator of the peace.”

²⁶ *Brown v. Hamilton County*, 126 S.W.3d 43, 48 (Tenn. Ct. App. 2003).

²⁷ *Wells*, 2005 WL 2007197, at *3.

²⁸ 221 S.W.3d. 14, 19 (Tenn. Ct. App. 2006).

²⁹ *Id.* at 27-28.

There are several sound public policy considerations advanced to explain and support the public duty doctrine.³⁰ One such public policy consideration is particularly instructive in the present litigation. Tennessee courts recognize that “individuals, juries, and courts are ill-equipped to judge governmental decisions as to how specific community resources should be or should have been allocated to protect individual members of the public.”³¹ To allow the Defendants to try a comparative fault defense against the Non-Party Governmental Entities for allegedly failing to shut down NECC prior to the fungal meningitis catastrophe would invite the jurors to attempt to answer the question of what resources the FDA, MBoP, TBoP and TDoH should have devoted to investigating one particular compounding pharmacy. Tennessee courts have long recognized that jurors are simply ill-equipped to answer such questions and that accountability of public agencies is better left to the political process.³²

Although the public duty doctrine frequently arises in the context of police officers sued for allegedly failing to enforce laws, the public duty doctrine applies to all governmental entities and employees that have a duty to enforce laws.³³ In fact, the Tennessee Court of Appeals recently applied the public duty doctrine in a similar context as the one at issue in the present

³⁰ *Eldridge v. City of Trenton*, 1997 WL 527303, at *2-4 (Tenn. Ct. App. Aug. 26, 1997) (discussing the public policy considerations behind Tennessee’s public duty doctrine).

³¹ *Id.* at *4.

³² *Hurd*, 221 S.W.3d at 20 (stating that public officials are “amenable only to the public, and punishable only by indictment for the breach of [duties]” owed to the public generally”) (emphasis added).

³³ *Karnes v. Madison Cnty*, 2010 WL 3716458, at *3 (Tenn. Ct. App. Sept. 23, 2010) (“Succinctly stated, the [public duty] doctrine provides that private citizens cannot maintain an action against public officials or entities unless they are able to allege a special duty not owed to the public generally.”) (*citing Hurd* 221 S.W.3d at 28); *Wells*, 2005 WL 2007197, at *3. (“In Tennessee, it has long been held that a plaintiff must show the existence of a duty particular to him or her, as distinct from a duty owed to the public in general.” In other words, under the public duty doctrine, “a duty owed to everyone is a duty owed to no one.”); *Lynch v. Loudon Cty.*, 2011 WL 4952778, at *5 (Tenn. Ct. App. Oct. 14, 2011) (“The public duty doctrine shields a public employee from lawsuits alleging liability for a breach of that employee’s duty owed to the public at large.”) (*citing Ezell*, 902 S.W.2d 394).

litigation. In *Kemper v. Baker*, the Tennessee Court of Appeals held that a building inspector could not be attributed any fault in a case in which the plaintiff alleged negligence based on “the failure of the city and the city manager to enforce certain OSHA regulations and provisions of the municipal building code.”³⁴ The Court of Appeals held that the city could not be liable for any negligent failure to enforce the building codes under the public duty doctrine.³⁵

Moreover, federal courts routinely apply the public duty doctrine of state courts to actions of federal agencies, officials, and governmental entities. The Fourth, Seventh, Eighth, and Ninth Circuit Courts of Appeals have all applied state law public duty doctrines in cases involving claims that agents of the United States government failed to properly enforce federal law.³⁶

“As in any other negligence action, a [party] must establish the existence of a duty or standard of care in an action for negligence of a government employee.”³⁷ “In Tennessee, it has long been held that a plaintiff must show the existence of a duty particular to him or her, as distinct from a duty owed to the public in general.”³⁸ Accordingly, because the Defendants cannot establish the required element of individual duty, those Defendants cannot ascribe fault to the governmental regulators at trial, and those regulators cannot be placed on the verdict form.

CONCLUSION

Tennessee law does not allow the Defendants to blame the government at trial. For the forgoing reasons, the PSC requests the entry of judgment on the pleadings dismissing the

³⁴ *Kemper v. Baker*, 2012 WL 1388371, at *1 (Tenn. Ct. App. Apr. 19, 2012).

³⁵ *Id.* at *6.

³⁶ *Fla. Auto Auction of Orlando, Inc. v. United States*, 74 F.3d 498, 503 (4th Cir. 1996); *Stratmeyer v. United States*, 67 F.3d 1340, 1347 (7th Cir. 1995); *Sorace v. United States*, 788 F.3d 758, 766 (8th Cir. 2015); *Saunders v. United States*, 99 F. App'x 814, 816 (9th Cir. 2004); *see also Perez v. Gov't of the Virgin Islands*, 847 F.2d 104 (3d Cir. 1988).

³⁷ *Wells*, 2005 WL 2007197, at *3.

³⁸ *Id.*

Defendants' alleged affirmative defense of comparative fault against the Food and Drug Administration, the Massachusetts Board of Registration in Pharmacy, the Tennessee Board of Pharmacy, and the Tennessee Department of Health.

Date: December 29, 2016

Respectfully submitted,

/s/ Benjamin A. Gastel

J. Gerard Stranch, IV
Benjamin A. Gastel
Anthony A. Orlandi
BRANSTETTER, STRANCH &
JENNINGS, PLLC
223 Rosa L. Parks Ave., Suite 200
Nashville, TN 37203
Telephone: 615/254-8801
Facsimile: 615/255-5419
gerards@bsjfirm.com
beng@bsjfirm.com
aorlandi@bsjfirm.com

Plaintiffs' Steering Committee and Tennessee State Chair

Thomas M. Sobol
Kristen Johnson Parker
HAGENS BERMAN SOBOL SHAPIRO, LLP
55 Cambridge Parkway, Suite 301
Cambridge, MA 02142
Telephone: 617/482-3700
Facsimile: 617/482-3003
tom@hbsslaw.com
kristenjp@hbsslaw.com

Plaintiffs' Lead Counsel

Elizabeth J. Cabraser
Mark P. Chalos
LIEFF CABRASER, HEIMANN & BERNSTEIN, LLP
275 Battery Street, 29th Floor
San Francisco, CA 94111
Telephone: 415/956-1000
Facsimile: 415/956-1008
ecabraser@lchb.com

mchalos@lchb.com

Federal/State Liaison

Marc E. Lipton
LIPTON LAW
18930 W. 10 Mile Road
Southfield, MI 48075
Telephone: 248/557-1688
Facsimile: 248/557-6344
marc@liptonlaw.com

Kimberly A. Dougherty
JANET, JENNER & SUGGS, LLC
31 St. James Avenue, Suite 365
Boston, MA 02116
Telephone: 617/933-1265
kdougherty@myadvocates.com

Mark Zamora
ZAMORA FIRM
6 Concourse Parkway, 22nd Floor
Atlanta, GA 30328
Telephone: 404/451-7781
Facsimile: 404/506-9223
mark@markzamora.com

Patrick T. Fennell
CRANDALL & KATT
366 Elm Avenue, S.W.
Roanoke, VA 24016
Telephone: 540/342-2000
Facsimile: 540/400-0616
pfennell@crandalllaw.com

Plaintiffs' Steering Committee

CERTIFICATE OF SERVICE

I, Benjamin A. Gastel, hereby certify that I caused a copy of the foregoing document to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Date: December 29, 2016.

/s/ Benjamin A. Gastel

Benjamin A. Gastel